**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| PAUL MONROE JAMES, III,<br><br>*Plaintiff,*<br><br>v.<br><br>UNITED STATES OF AMERICA, *et al.*,<br><br>*Defendants.* | CIVIL ACTION<br>NO. 19-04627 |

**PAPPERT, J.** **April 2, 2020**

**MEMORANDUM**

Paul James sued the United States and Siemens Medical Solutions USA, Inc., after a Siemens Symbia Evo machine crushed his feet during an imaging study at a Veterans Administration hospital. In addition to asserting negligence claims against the United States, James seeks to hold Siemens strictly liable for its alleged failure to properly design and manufacture the Symbia Evo or warn of its dangers. These failures, James claims, also breached the implied warranties of merchantability and fitness for a particular purpose. Siemens moves to dismiss the claims, arguing that Pennsylvania law does not recognize claims for strict liability or breach of implied warranty against medical device manufacturers. Alternatively, Siemens contends that James failed to allege facts sufficient to state such claims. The Court disagrees and denies the Motion in all but two respects.

I

James went to a Philadelphia VA hospital for a stress test. (Compl. ¶ 16, ECF No. 1.) After that test, a hospital employee placed James in a Symbia Evo machine for

an imaging study. (*Id.* at ¶ 17.) But James was so tall that his feet hung over the edge of the machine. (*Id.* at ¶¶ 18–19.) As the machine started to move, it crushed James's feet, causing serious and possibly lifelong injuries. (*Id.* at 20.)

In his Complaint, James attributes his injuries to the Symbia Evo machine's defective design and manufacture and Seimens's failure to warn of the machine's dangers. *See* (*id.* at ¶¶ 41–47). As for the design defect, James points to Siemens's failure to include various safety features, such as "a guard, sensor or kill switch" or other mechanism "to warn when the risk of a crush injury would occur during use." (*Id.* at ¶ 44.) He claims that Siemens defectively manufactured the Symbia Evo machine's "warming cabinet and component parts." (*Id.*) Siemens's failure to warn, James says, consists of its failure to provide (1) instructions on how to safely use the machine; (2) "appropriate size and height requirements"; and (3) other "conspicuous and adequate warnings." (*Id.* at ¶ 44.) For these alleged failures, James seeks to hold Siemens strictly liable. *See* (*id.* at ¶¶ 41–47). He adds that Siemens's conduct also breached the implied warranty of merchantability and fitness for a particular purpose. (*Id.* at ¶ 49.)

Siemens moves to dismiss all claims. It argues that, as a manufacturer of medical devices, it cannot be held strictly liable for James's injuries or for breach of implied warranty under Pennsylvania law. *See* (Mot. to Dismiss 3–9, ECF No. 11). Alternatively, Siemens contends that James failed to allege facts sufficient to state such claims. (*Id.* at 10–16.)

II

To avoid dismissal under Rule 12(b)(6), a complaint must "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible if the plaintiff pleads facts from which the Court can infer

"that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Though this "plausibility standard is not akin to a 'probability requirement,'" it demands "more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Twombly*, 550 U.S. at 556).

Assessing plausibility under *Twombly* and *Iqbal* is a three-step process. *See Connelly v. Lane Const. Corp.*, 809 F.3d 780, 787 (3d Cir. 2016). Step one is to "take note of the elements the plaintiff must plead to state a claim." *Id.* (alterations omitted) (quoting *Iqbal*, 556 U.S. at 675). Next, the Court "should identify allegations that, 'because they are no more than conclusions, are not entitled to the assumption of truth.'" *Id.* (quoting *Iqbal*, 556 U.S. at 679). Finally, for all "well-pleaded factual allegations, the court should assume their veracity," draw all reasonable inferences from them "and then determine whether they plausibly give rise to an entitlement to relief." *Id.* (alterations omitted) (quoting *Iqbal*, 556 U.S. at 679). If the well-pleaded facts do not nudge the "claims across the line from conceivable to plausible," the Court must dismiss the complaint. *Twombly*, 550 U.S. at 570.

III

A

When a federal court exercises supplemental jurisdiction over state-law claims, it applies the forum state's substantive law. *See Chin v. Chrysler LLC*, 538 F.3d 272, 278 (3d Cir. 2008). The rulings of a state's highest court "are the authoritative source" on state law. *In re Trs. of Conneaut Lake Park, Inc.*, 855 F.3d 519, 522 (3d Cir. 2017) (quoiting *Spence v. ESAB, Grp.*, 623 F.3d 212, 216 (3d Cir. 2010)). Lacking such a ruling, a federal court must predict how the state's highest court would rule. *See id.* at 522–23. In doing so, it must "consider relevant state precedents, analogous decisions,

considered *dicta*, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand." *Packard v. Provident Nat'l Bank*, 994 F.2d 1039 (3d Cir. 1993) (quoting *McKenna v. Ortho Pharm. Corp.*, 622 F.2d 657, 663 (3d Cir. 1980)). Although not binding, rulings by the state intermediate appellate courts should not be disregarded unless the federal court is convinced by other persuasive data that the highest court of the state would decide otherwise." *N. Ins. Co. of New York v. Aardvark Assocs., Inc.*, 942 F.2d 189, 193 (3d Cir. 1991) (quoting *West v. American Telephone & Telegraph Co.*, 311 U.S. 223, 237 (1940)).

Pennsylvania law follows § 402A of the Restatement (Second) of Torts. *See Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 382 (Pa. 2014). Under that section, "[o]ne who sells any product in a defective condition unreasonably dangerous to the user" is strictly liable for any injuries the product causes. Restatement (Second) of Torts § 402A(1). Because "[n]o product is expressly exempt" from § 402A, Pennsylvania courts presume that "strict liability may be available with respect to any product, provided that the evidence is sufficient to prove a defect." *Tincher*, 104 A.3d at 382.

Comment k to § 402A notes that some products, however, are "incapable of being made safe for their intended and ordinary use." Restatement (Second) of Torts § 402A, cmt. k. "The seller of such products," the comment continues, should not "be held to strict liability for unfortunate consequences attending their [products'] use" so long as the products "are properly prepared and marketed, and proper warning is given." *Id.* Comment k counsels that its qualified exception to strict liability applies to only "[u]navoidably unsafe products," most notably prescription drugs. *Id.*

Relying on Comment k, the Pennsylvania Supreme Court in *Hahn v. Richter*,

673 A.2d 888 (Pa. 1996), held that prescription drug manufacturers cannot be held strictly liable for failing to adequately warn of a drug's dangers. *Id.* at 891. *Hahn* read Comment k as denying "strict liability to products such as prescription drugs . . . when marketed with proper warnings." *Id.* at 889–90. And as Comment j counseled, a warning is inadequate only when the manufacturer is negligent—that is, fails "to exercise reasonable care to warn of dangers." *Id.* at 891. Though *Hahn* spoke only of a failure-to-warn claim, the Pennsylvania Supreme Court has read *Hahn* to preclude all strict-liability claims against prescription drug manufacturers. *See, e.g.*, *Lance v. Wyeth*, 85 A.3d 434, 438 (Pa. 2014).

Siemens asks the Court to extend *Hahn* and immunize medical device manufacturers from all strict-liability claims. *See* (Mot. to Dismiss 3–9). For support, Siemens invokes *Creazzo v. Medtronic, Inc.*, 903 A.2d 24 (Pa. Super. Ct. 2006). The trial court there had concluded that a medical device implanted into the plaintiff's spine was an unavoidably unsafe product within Comment k's ambit. *See id.* at 31. And finding no relevant distinction between the device at issue and prescription drugs as discussed in *Hahn*, the trial court dismissed the plaintiff's strict-liability claims against the device manufacturer. *See id.* The Superior Court affirmed this conclusion, noting that it could "find no reason why the same rational application to prescription drugs may not be applied to medical devices." *Id.* Siemens argues that this statement, together with *Hahn*, has created "an absolute bar to strict liability claims against both prescription drug and medical device manufacturers." (Mot. to Dismiss 4.)

First, it is unclear that the Symbia Evo machine even is a "medical device," as Pennsylvania law uses the term. The Third Restatement defines "medical device" as

"one that may be legally sold or otherwise distributed only pursuant to a health-care provider's prescription." Restatement (Third) of Torts § 6(a). Though Pennsylvania follows the Second, not Third, Restatement, *see Tincher*, 64 A.3d at 309, this conception of medical devices explains why Pennsylvania's suggested jury instructions for prescription drugs and medical devices speak of a "prescribing" or "implanting" physician. Pa. Suggested Standard Civil Jury Instructions § 23.20. It also accounts for the federal-court cases dealing with implantable devices that conclude Pennsylvania law immunizes medical device manufacturers from various strict-liability claims.[1]

Even if the Symbia Evo machine is a medical device, *Creazzo* likely does not stand for the broad proposition that Siemens thinks it does. "[I]t is axiomatic that the holding of a judicial decision is to be read against its facts." *Lance*, 85 A.3d at 264. The medical device in *Creazzo* was implanted into the plaintiff's spinal cord to send electrical pulses through nerve structures. *See* 903 A.2d at 26. On those facts, the Superior Court affirmed the trial court's conclusion that it could not distinguish this unavoidably unsafe device from the prescription drug in *Hahn* and discussed by Comment k. *See id.* at 31. *Creazzo*'s holding does not create a blanket rule for all medical devices, and the decision is little help to Siemens given the difference between the Symbia Evo machine and the device in *Creazzo*.

In any event, the Pennsylvania Supreme Court's more recent guidance further

[1] *See, e.g.*, *Kohn v. Ethicon, Inc.*, No. CV 19-40004, 2020 WL 733126, at *1 (E.D. Pa. Feb. 13, 2020) (implantable pelvic mesh device); *Rosenberg v. C.R. Bard, Inc.*, 387 F. Supp. 3d 572, 577 (E.D. Pa. 2019) (same); *Buck v. Endo Pharm., Inc.*, No. CV 19-837, 2019 WL 1900475, at *1 (E.D. Pa. Apr. 29, 2019) (same); *Wagner v. Kimberly-Clark Corp.*, 225 F. Supp. 3d 311, 315 n.3 (E.D. Pa. 2016) (feeding tube); *Wilson v. Synthes USA Prods., LLC*, 116 F. Supp. 3d 463, 465–67 (E.D. Pa. 2015) (spinal fixation rods); *Terrell v. Davol, Inc.*, No. CIV.A. 13-5074, 2014 WL 3746532, at *3–5 (E.D. Pa. July 30, 2014) (hernia mesh); *Geesey v. Stryker Corp.*, No. CIV.A. 09-2988, 2010 WL 3069630, at *2–5 (E.D. Pa. Aug. 4, 2010) (implantable pain pump).

undermines Siemens's argument. That court has cautioned against unthinkingly stretching "principles beyond scenarios to which they rationally relate." *Lance*, 85 A.3d at 264. Such blanket judicial lawmaking is particularly unwise without a record containing a "comprehensive discussion of the competing policies" and empirical data that might "support an informed, legislative-type judgment." *Id.* at 265. Even with a robust record, courts "address evidence and arguments in individual cases"; they are ill-suited to decide if whole categories of products should be exempt from liability. *Tincher*, 104 A.3d at 409. Indeed, the Pennsylvania Supreme Court has singled out *Hahn*'s "truncated analysis" of Comment k as "a poor foundation for extrapolation." *Lance*, 85 A.3d at 261 n.21.

B

1

Strict liability applies to three types of defects: design, manufacturing and failure-to-warn. *Phillips v. A-Best Prods. Co.*, 665 A.2d 1167, 1170 (Pa. 1995). To state a strict-liability claim, a plaintiff must allege "that the product was sold in a defective condition 'unreasonably dangerous' to the user, and that the defect caused plaintiff's injury." *Id.* at 1171 (quoting *Walton v. Avco Corp.*, 610 A.2d 454, 458 (Pa. 1992)). A product has a design defect if: (1) it poses a danger that is unknowable and unacceptable to the average or ordinary consumer, or (2) "a reasonable person would conclude that the probability and seriousness of harm caused by the product outweigh the burden or costs of taking precautions." *Tincher v. Omega Flex, Inc.*, 180 A.3d 386, 397 (Pa. Super. Ct. 2018). To state a claim for failure-to-warn, "a plaintiff must show that a warning of a particular danger was either inadequate or altogether lacking, and that this deficiency in warning made the product 'unreasonably dangerous.'" *Phillips*,

665 A.2d at 1171. As for causation, a failure-to-warn claim requires a showing "that the user of the product would have avoided the risk had he or she been warned of it by the seller." *Id.* A manufacturing defect requires either direct evidence of "a breakdown in the machine or a component thereof," *Riley v. Warren Mfg., Inc.*, 688 A.2d 221, 224 (Pa. 1997), or circumstantial evidence that the machine malfunctioned, along with "evidence eliminating abnormal use or reasonable, secondary causes for the malfunction," *Rogers v. Johnson & Johnson Prods., Inc.*, 565 A.2d 751, 754 (Pa. 1989).

Though relatively sparse, James's Complaint alleges enough facts to state a strict-liability design-defect claim against Siemens. He contends that the Symbia Evo machine's defective design left it "in an unreasonably dangerous, defective and unsafe condition." (Compl. ¶ 42.) Specifically, he points to the lack of "a guard, sensor or kill switch," as well as other safety mechanisms. (*Id.* ¶ 44.) And one may reasonably infer from these allegations that the Symbia Evo machine posed an unknown danger—crushing patients' feet—that would be unacceptable to the average consumer. *See, e.g.*, (*id.* at ¶¶ 18–20, 42–46).

These facts also nudge James's failure-to-warn claim across the line from conceivable to plausible. He alleges that Siemens inadequately or entirely failed to warn of the machine's foot-crushing potential for tall patients. *See* (Compl. ¶ 44). This failure, James claims, both rendered the machine unreasonably dangerous for tall patients and caused his injuries. (*Id.* at ¶¶ 44–46.) One may reasonably infer from these allegations that, had James known of this danger, he would not have used the machine. *See* (*id.*)

James's manufacturing-defect claim, however, fails to cross the plausibility

threshold. Though James baldly asserts that the machine's "warming cabinet and component parts" were "manufactured and sold in a defective and dangerous manner," he never alleges that the machine or any component broke down or malfunctioned. (*Id.* at 44.) Nor do his conclusory allegations allow an inference that the machine somehow malfunctioned during the imaging study. To the contrary, James alleges that the hospital employee misused the machine. *See, e.g.*, (*id.* at ¶ 31).

2

Pennsylvania's Commercial Code codifies the implied warranty of merchantability, which requires goods to be "free from significant defects." *Gall v. Allegheny Cty. Health Dep't*, 555 A.2d 786, 789 (Pa. 1989); *see* 13 Pa. Cons. Stat. § 2314. The elements of a breach-of-implied-warranty claim are identical to those of a strict-liability claim. *See Altronics of Bethlehem, Inc. v. Repco, Inc.*, 957 F.2d 1102, 1105 (3d Cir. 1992). Because James has stated plausible strict-liability claims for design and failure-to-warn defects, it follows that he has also stated a plausible breach-of-implied-warranty-of-merchantability claim.

Pennsylvania law also recognizes an implied warranty of fitness for a particular purpose. 13 Pa. Cons. Stat. § 2315. This warranty "is based upon a special reliance by the buyer on the seller to provide goods that will perform a specific use envisaged and communicated by the buyer." *Gall*, 555 A.2d at 790. It applies if a seller has reason to know that the buyer requires the goods for a particular purpose and the buyer relies "on the skill or judgment of the seller to select or furnish suitable goods." 13 Pa. Cons. Stat. § 2315. A "particular purpose" involves "a specific use by the buyer which is peculiar to the nature of his business." *Id.* cmt. 2. A product's "ordinary purpose," by contrast, includes those purposes for which the product is customarily used. *Id.*

James fails to allege that the hospital intended to use the Symbia Evo machine for a "particular purpose" other than its ordinary purpose of performing imaging studies on patients. Nor does he allege that Siemens knew of this unstated purpose.

IV

A court should grant a plaintiff leave to amend a complaint "when justice so requires." Fed. R. Civ. P. 15(a)(2). This rule expresses "a preference for liberally granting leave to amend" unless "amendment would cause undue delay or prejudice, or that amendment would be futile." *Oran v. Stafford*, 226 F.3d 275, 291 (3d Cir. 2000). Siemens argues that amendment would be futile because the statute of limitations ran in late November of 2019. *See* (Mot. to Dismiss 7 n.3). But an amended "pleading relates back to the date of the original pleading when . . . the amendment asserts a claim or defense that arose out the conduct, transaction, or occurrence set out—or attempted to be set out—in the original pleading." *Id.* 15(c)(1)(B). Because James's amendment would merely clarify and expand on allegations relating to existing claims, it relates back and poses no statute-of-limitations problems. Thus, granting James leave to amend his dismissed claims would be neither inequitable nor futile.

An appropriate Order follows.

BY THE COURT:

***/s/ Gerald J. Pappert***
GERALD J. PAPPERT, J.